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ROBERT, EDUARDO C

FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 4002-2950/PC464.00 5676 10/083,199 02/26/2002 Hai Trieu

Indianapolis, IN 46201-5137

EXAMINER

PAPER NUMBER

12/13/2004 Woodard, Emhardt, Naughton, Moriarty and McNett

Bank One Center/Tower **Suite 3700** 111 Monument Circle

ART UNIT

3732

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | |
|---|--|---|----------|
| | 10/083,199 | TRIEU ET AL. | |
| Office Action Summary | Examiner | Art Unit | |
| | Eduardo C. Robert | 3732 | |
| The MAILING DATE of this communication apperiod for Reply | pears on the cover sheet wit | h the correspondence address | i |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a rep - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailine earned patent term adjustment. See 37 CFR 1.704(b). | I36(a). In no event, however, may a re ly within the statutory minimum of thirty will apply and will expire SIX (6) MONT e, cause the application to become ABA | ply be timely filed (30) days will be considered timely. 'HS from the mailing date of this communi NDONED (35 U.S.C. § 133). | ication. |
| Status | | | |
| 1) Responsive to communication(s) filed on 9/13 | V04. | | |
| , | s action is non-final. | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | |
| Disposition of Claims | | | |
| 4) | Sand 89 is/are withdrawn from is/are rejected. | om consideration. | |
| 9)☐ The specification is objected to by the Examin 10)☒ The drawing(s) filed on 26 February 2002 is/a Applicant may not request that any objection to the | re: a)⊠ accepted or b)⊡ c e drawing(s) be held in abeyan | ce. See 37 CFR 1.85(a). | 121(d) |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of: 1. Certified copies of the priority documer 2. Certified copies of the priority documer 3. Copies of the certified copies of the priority documer application from the International Burea * See the attached detailed Office action for a list | ats have been received. ats have been received in Apority documents have been au (PCT Rule 17.2(a)). | oplication No received in this National Stag | e |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 6/14/02,11/4/02. | Paper No(s | ummary (PTO-413))/Mail Date nformal Patent Application (PTO-152) |) |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I, i.e. claims 1-38 and new claims 78-97, and Species I, i.e. Figure 1, in the reply filed on September 13, 2004 is acknowledged.

It is acknowledged applicant's believe that claims 1-9, 12-14, 33, 35, 37, 38, and 78-97 read on the elected Species. It is noted that comparison of the claims with Species I, i.e. Figure 1, and the specification shows, however, that the species of Figure 1 does not have an artificial ligament as required in claims 8, 9, 12-14, 85, and 86. Also, the species of Figure 1 does not have an implant comprising a substantially inelastic material as required in claims 37 and 89.

Claims 8-32, 34, 36, 37, 85, 86, and 89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention and Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 13, 2004.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-7, 33, 35, 38 and 97 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 1, lines 2-3, applicant positively recites part of a human, i.e. "at least a portion of one of said first and second ends positioned in a tunnel formed in a first

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vertebral body", and in line 4, applicant positively recites part of a human, i.e. "at least one anchor engaged to the first vertebral body. In claim 2, lines 1 and 2, applicant positively recites part of a human, i.e. "said at least one anchor is embedded in the tunnel". In claim 3, lines 1-4, applicant positively recites part of a human, i.e. "the other of said first and second ends of said implant is embedded in a second tunnel formed in a second vertebral body a second anchor engaged to the second vertebral body attaching said implant to the second vertebral body". In claim 4, lines 1 and 2, applicant positively recites part of a human, i.e. "a device positioned in a spinal disc space between the first vertebral body and the second vertebral body". In claim 97, lines 1 and 2, applicant positively recites part of a human, i.e. 'said body extends along anterior faces of the first vertebral body and the second vertebral body". Thus claims 1-7, 33, 35, 38, and 97 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 33, 35, 38, 78-84, 87, 88, and 90-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1, line 4, "said one end" is indefinite because it is unclear to what end applicant is referring to, e.g. first end, second end, or at least a portion of one of said first and second ends.

In claim 5, lines 1 and 2, "the axial plane of the spinal column" lacks a prior antecedent.

In claim 78, lines 6 and 7, "the axial plane of the spinal column" lacks a prior antecedent.

In claim 91, line 7, "the axial plane of the spinal column" lacks a prior antecedent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

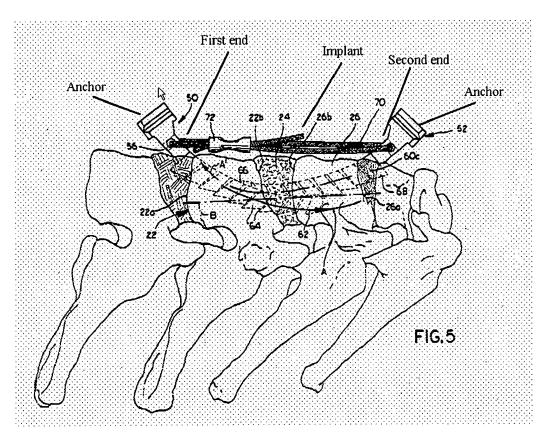
Claims 1-7, 33, 35, 38, 78-84, 87, 88, and 90-97, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Steffee (U.S. Patent 4,790,303).

Steffee discloses a system comprising an implant with first and second ends, and two anchors (see Figure 5 below). The system further comprises a device 24. With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Steffee which has the ability of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). Also, with regard to the phrases "adapted for" it has been held that the recitation that an element is "adapted for"

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perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. In the instant case the system of Steffee has the ability to perform the function recited in the claims if one so desire.



Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719.

The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eduardo C. Robert Primary Examiner Art Unit 3732

E.C.R.